ELabELN | Template Use Case White Paper

HPLC Experiment Template

Structured Documentation for Reverse-Phase Assay — From Mobile-Phase Prep Through System-Suitability and Assay-Result Calculation

APPLIES TO

- Analytical chemistry and pharmaceutical QC laboratories
- Food & beverage testing and chemical-industry labs
- Analytical method-development groups
- Contract research and testing organizations (CROs)

RELEVANT COMPLIANCE & INTEGRITY FRAMEWORKS

- FDA 21 CFR Part 11 — Electronic records and signatures
- GLP / GMP — Good laboratory and manufacturing practice
- ISO/IEC 17025 — Testing and calibration laboratory competence
- ICH Q2(R1) — Analytical method validation

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1. Executive Summary

An HPLC assay result — the potency of a tablet, the purity of an ingredient, the concentration of an analyte — is a number that other people act on: a batch is released, a formulation is accepted, a method is transferred. In regulated analytical work, that number is only defensible if the method, the system-suitability check, and the reagent and column provenance behind it are all documented and attributable. System suitability is the gate: unless the tailing factor, theoretical plates, resolution, and replicate-injection precision meet the method's criteria, the run is invalid and the result cannot be used. Capturing that gate, the validated method version it was run against, and the standard and column lots is the difference between a result that survives an audit and one that does not.

The ELabELN HPLC Experiment Template solves this by providing a pre-built, fully structured assay record that loads from the template library in a single click. It ships with a 10-step USP-style protocol, validated method references, pre-wired system-suitability fields, and typed inputs for column chemistry, mobile phase, flow rate, detection wavelength, retention times, peak areas, and assay results. Column lots, mobile-phase preparations, and reference standards link to the ELabELN inventory, and the tamper-evident audit trail captures every method version, every system-suitability run, and every assay calculation.

This white paper describes what the template contains, the analytical use case it is designed to support, the upstream and downstream workflows it connects to, the benefits it delivers to the analyst, and how a laboratory can deploy it and begin running assays within days.

> **KEY BENEFIT**
> Labs that adopt the HPLC template stop restating the method from scratch every batch, capture column-life, standard-prep, and method-version provenance automatically, and gain queryable system-suitability and assay-result history — the audit-ready documentation that GMP, ISO 17025, and analytical method transfer require, with every result anchored to the validated method version it was run against.

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2. What Is Reverse-Phase HPLC, and Why Does Documentation Matter?

2.1 The Technique

High-performance liquid chromatography separates the components of a sample by pumping it, dissolved in a mobile phase, through a column packed with a stationary phase. In reverse-phase HPLC the stationary phase is non-polar (typically a C18-bonded silica) and the mobile phase is a polar mixture — here a phosphate buffer with methanol — so analytes elute in order of decreasing polarity. As each component leaves the column it passes a detector (UV at 254 nm in this method), producing a chromatogram of peaks whose retention times identify the analytes and whose areas quantify them, usually against a reference standard and an internal standard such as caffeine.

Before any result is reported, the run must pass system suitability — a set of compendial checks that confirm the chromatographic system is performing as the validated method requires. The tailing factor confirms peak symmetry, the theoretical-plate count confirms column efficiency, the resolution confirms that adjacent peaks are separated, and the relative standard deviation of replicate injections confirms injection precision. If any of these fails, the run is invalid, regardless of what the sample peaks appear to show.

This is what makes HPLC documentation different from a research assay: **the result is only valid if it was produced under a validated method that passed system suitability, so the method version, the suitability metrics, and the standard and column lots must travel with every result — not as a printout, but as attributable, queryable data.**

2.2 The Documentation Problem

Recording HPLC assays on instrument printouts and in a paper notebook creates a set of interconnected risks:

- The method is restated by hand each batch, so which validated method version a result was run against is uncertain — a serious gap for method transfer and audit.
- System-suitability metrics are noted on a printout, so a lab cannot show at a glance that every reported result was preceded by a passing suitability check.
- Column lot and cumulative injection count (column life), mobile-phase preparation, and reference-standard lot are not captured against the run, so a drifting result cannot be traced to an aging column or a new standard.
- Retention times, peak areas, and assay calculations live in separate files, disconnected from the method and suitability record.
- There is no timestamped, attributed record of who ran and who reviewed each assay — the authorized-review step regulated work requires.
- Prior batches run under the same method cannot be retrieved to trend system suitability, so a slow degradation is invisible until a run fails.

These are the gaps that make an HPLC result hard to defend, and they are the gaps this template was designed to close.

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3. Template Overview: What Ships with the Template

The ELabELN HPLC Experiment Template is a pre-populated experiment record available to all ELabELN subscribers directly from the template library. It ships configured for the USP assay method for acetaminophen quantification in formulated tablets, with a 10-step protocol covering mobile-phase preparation through final assay-result calculation and system-suitability documentation. The default method assumes isocratic reverse-phase chromatography on a C18 column (4.6 × 150 mm, 5 µm), a phosphate buffer + methanol mobile phase, UV detection at 254 nm, caffeine as internal standard, and a five-point standard curve from a working reference standard. Every section is editable — the configuration is a tested baseline, not a locked format.

3.1 Template Sections at a Glance

The template populates the existing ELabELN experiment sections your lab already works in. Your team edits a working baseline instead of restating the method from scratch every batch.

Section	What it pre-populates
Main Text	Method summary, column and mobile-phase notes, and expected results, authored in the TinyMCE rich-text editor and linked to sample weighing and the method-validation reference.
Extra Fields	Twelve structured, typed fields grouped as Method, Sample, and System Suitability — column chemistry and dimensions, mobile-phase composition, flow rate, injection volume, detection wavelength, retention times, peak areas, tailing factor, theoretical plates, and replicate-injection RSD. Typed values make method parameters and system performance queryable across runs.
Steps	A 10-step workflow checklist covering mobile-phase prep through assay-result calculation. Each tick is timestamped to the audit trail, and the instrument run is auto-logged.
Compounds	The reference standard, mobile-phase components, column, and internal standard pre-linked from the compound database, with lot numbers and the standard certificate carried in automatically and column-life tracking maintained.
Links & Resources	Pre-wired to the lab's validated method, the instrument IQ/OQ reference, and the system-suitability SOP.
Storage & Files	4 °C reference-standard aliquot storage and prepared mobile phase, plus labelled attachment slots for raw chromatogram exports and integrated peak tables (CSV + PDF).

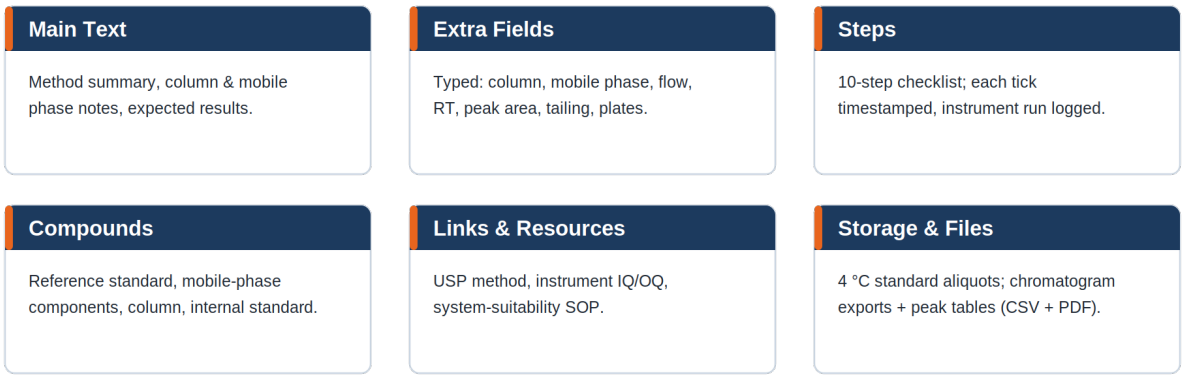
Main Text
Method summary, column & mobile phase notes, expected results.
Extra Fields
Typed: column, mobile phase, flow, RT, peak area, tailing, plates.
Steps
10-step checklist; each tick timestamped, instrument run logged.
Compounds
Reference standard, mobile-phase components, column, internal standard.
Links & Resources
USP method, instrument IQ/OQ, system-suitability SOP.
Storage & Files
4 °C standard aliquots; chromatogram exports + peak tables (CSV + PDF).

Figure 1. The six ELabELN experiment sections pre-populated by the HPLC template.

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3.2 The 10-Step Protocol

The workflow checklist is the operational spine of the template. Each step maps to a discrete bench or instrument action and writes a timestamped, user-attributed entry to the audit trail when checked off. The instrument run is auto-logged, and two steps are compliance checkpoints: the system-suitability evaluation that gates the run, and the authorized review and sign-off.

Step	Action	What it captures
1	Prepare mobile phase	Mobile-phase composition
2	Prepare standards	5-point curve; reference & internal standard
3	Prepare samples	Weigh / dissolve / filter; injection volume
4	Equilibrate column	Column chemistry / dimensions; flow rate
5	Inject system-suitability	Replicate injections
6	Evaluate system suitability	Tailing, plates, resolution, RSD (gate)
7	Inject sequence	Standards & samples
8	Integrate peaks	Retention times, peak areas (instrument / CDS)
9	Calculate assay result	Assay result (% of label claim)
10	Review & sign-off	Authorized review; e-signature

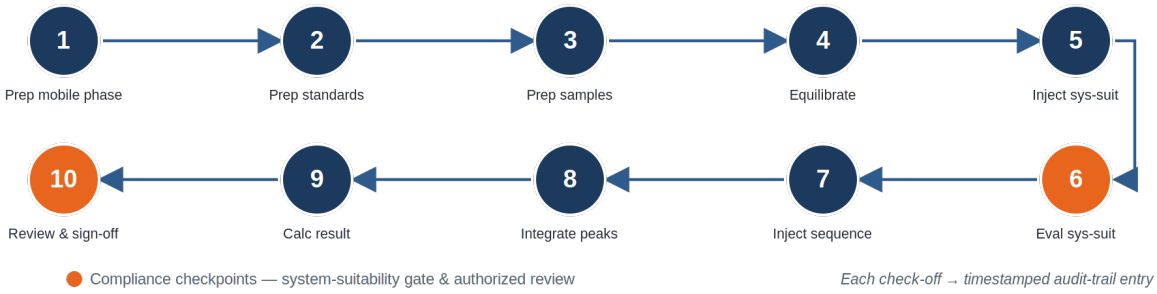

Figure 2. The 10-step reverse-phase HPLC workflow — orange steps are the compliance checkpoints (the system-suitability gate and authorized review); every check-off writes a timestamped entry to the ELabELN audit trail.

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4. The Use Case: When and How the Template Is Used

The template is intended as a tested baseline for analytical chemistry, pharmaceutical QC, food and beverage testing, and method-development labs running small-molecule quantification by reverse-phase HPLC. It is configured around a recognizable reference — a USP acetaminophen tablet assay — but the scenarios it serves span the analytical bench.

4.1 Pharmaceutical QC and Release Assays (Primary Use Case)

The core scenario: quantifying an active ingredient against a validated method to decide whether a batch meets specification. The template captures the method version, the system-suitability result, and the assay calculation in one attributable record, so a release decision rests on documented, defensible data rather than a printout stapled into a notebook.

4.2 Method Development

During development, analysts iterate on column, mobile phase, and gradient to resolve peaks and shorten run time. The template's typed method fields make each iteration a structured, comparable record, so the effect of a change on resolution and peak shape is visible across attempts rather than reconstructed from memory.

4.3 Method Validation (ICH Q2(R1))

For validation runs, the structured fields capture the precision, accuracy, linearity, range, LOD, and LOQ measurements required under ICH Q2(R1). The audit trail then links every subsequent routine assay to the validated method version, closing the loop between validation and routine use.

4.4 Food & Beverage and Chemical Testing

The same reverse-phase structure serves additives, contaminants, and ingredient assays in food, beverage, and chemical labs. Swap the analyte, column, and standard, and the method, sample, and system-suitability fields apply unchanged.

4.5 Method Transfer

Transferring a method between sites or instruments demands that both labs run the identical, documented method and demonstrate equivalent system suitability. Because the method and suitability criteria are captured as structured data, the template provides the shared, versioned reference a transfer protocol depends on.

4.6 Multi-Analyst and CRO Settings

Because every ELabELN edition includes unlimited users, the QC analyst, lab manager, method developer, and reviewing manager can all work from the same template, and the pre-wired SOP and validated method enforce one consistent procedure. Granular permissions let the lab manager decide who may edit method records versus only review them — the separation of duties that regulated analytical work and CRO client studies require.

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5. Dependencies and Connected Workflows

The HPLC template does not exist in isolation. It sits inside a network of connected workflows — upstream, parallel, external, and downstream — that give the assay record its full analytical and regulatory value.

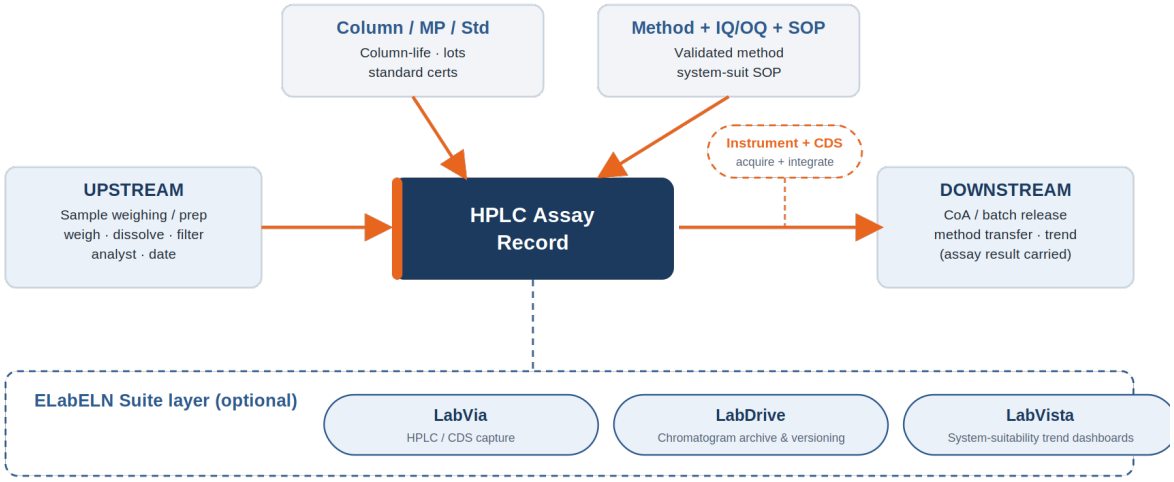

Figure 3. The template connects upstream sample weighing, parallel inventory and method/SOP systems, the external instrument and chromatography data system, and downstream release, method-transfer, and trend workflows.

5.1 Upstream: Sample Weighing and Preparation

Every assay begins with sample preparation — weighing tablets or material, dissolving, diluting, and filtering. The template links to the upstream weighing and prep record, so opening an assay surfaces the sample identity, the weights and dilutions, and the analyst and date, anchoring every result to the material and preparation behind it.

5.2 Parallel: Column, Mobile-Phase, and Reference-Standard Inventory

The Compounds section links the reference standard, mobile-phase components, the column, and the internal standard directly to the ELabELN inventory. Because column condition and standard identity drive result validity, this traceability is decisive. Through the link the record automatically carries:

- **Column lot and cumulative column-life**, so a drift in efficiency or resolution can be traced to an aging column.
- **Reference-standard lot and certificate**, shown inline, so the exact standard behind a result is documented.
- **Mobile-phase preparation and expiry**, with low-stock warnings before a run, so an assay is not started against an expired preparation.

Barcode and QR scanning can populate these links from the physical vial or column, keeping lot capture effortless.

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5.3 Parallel: Validated Method, IQ/OQ, and System-Suitability SOP

The Links section connects the assay to the lab's validated method, the instrument IQ/OQ qualification reference, and the system-suitability SOP. Because the method is version-controlled in ELabELN, every assay records which method version it was run against — the anchor that method transfer and audit both depend on.

5.4 External: The Instrument and Chromatography Data System

The HPLC instrument and its chromatography data system (CDS) acquire the chromatogram and integrate the peaks. ELabELN is the system of record around that acquisition: the method parameters, the system-suitability metrics, the retention times and peak areas, and the calculated assay result are captured as typed fields, and the raw chromatogram export and integrated peak table attach to the record. The full sample run — retention times, peak areas, and calculated results — lives in the spreadsheet editor as a single structured grid, keeping the method, the raw data, and the result together.

5.5 Downstream: CoA, Batch Release, Method Transfer, and Trend

The assay result feeds certificates of analysis, batch-release decisions, method-transfer protocols, and — because the results and suitability metrics are typed and queryable — system-suitability trend analysis across batches. A drifting column or standard shows up in the trend before it causes a failed run.

5.6 The ELabELN Suite: Instruments and Dashboards

Everything above is available in ELabELN Standard. Labs on the ELabELN Suite gain three layers that connect to the same record: LabVia captures data directly from the HPLC and its CDS; LabDrive adds metadata search, versioning, and role-based access across chromatogram archives; and LabVista builds system-suitability trend dashboards on the structured method and suitability metadata. The same audit trail and data-integrity controls span all layers.

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6. How the Analyst Benefits

The template is built to deliver value at the bench and to the quality system alike. The benefits compound with every batch a lab runs.

6.1 Start From a Tested Baseline, Not a Restated Method

The scaffold — protocol, typed method fields, column and standard links, validated-method and SOP references — is already built. The analyst edits a working configuration to match the assay they actually run, rather than restating the method from scratch every batch. The first assay is faster, and every subsequent one is consistent with the validated method.

6.2 Document by Doing

Checking off each of the 10 steps as it happens produces a contemporaneous, timestamped record as a by-product of the assay, and the instrument run is auto-logged. There is no separate write-up to reconstruct later.

6.3 Never Lose Method-Version or Lot Provenance Again

Because the column, standard, and mobile phase are linked to inventory and the method is version-controlled, the method version, standard lot and certificate, and column life are captured automatically on every assay. When a result is questioned, the full provenance is on the record — closing the most consequential analytical-QC gap by default.

6.4 System-Suitability and Result Trends You Can Query

Typed method, suitability, and result fields make QC queryable. An analyst or reviewer can pull every batch run under a method version, trend the tailing factor, plate count, resolution, and RSD, and catch a drifting system before it produces an invalid run — instead of discovering it when suitability finally fails.

6.5 Produce Audit-Ready Records for GMP, ISO 17025, and Transfer

The tamper-evident audit trail, version-controlled method linkage, and electronic signatures mean the record that results from normal use is already structured to support method-validation documentation, ISO 17025 and 21 CFR Part 11 review, and analytical-method-transfer protocols. Compliance ownership remains with the lab's quality program; the template supports it by default.

> **AT THE BENCH, IN PRACTICE**
> A QC analyst opens the template, confirms it references the current validated method version, scans the column and reference-standard to capture their lots and the standard certificate, and checks off each step. After the suitability injections, the tailing factor, plate count, resolution, and RSD go into typed fields — and the run proceeds only because they pass. The assay result is calculated, the chromatogram attached, and the reviewing manager signs off electronically. The batch record now holds the method, the passing suitability, and the result together, ready for audit.

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7. The Chromatogram, System Suitability, and Assay Result

7.1 The Default Reference: A USP Acetaminophen Assay

The template ships configured for the USP acetaminophen tablet assay — isocratic reverse-phase separation on a C18 column with a phosphate buffer + methanol mobile phase, UV detection at 254 nm, and caffeine as internal standard. Before results are reported, the run must pass system suitability: a tailing factor within limits (typically ≤ 2.0), a theoretical-plate count above the method minimum (≥ 2000), resolution between adjacent peaks (≥ 2.0), and replicate-injection RSD within tolerance (≤ 2.0%). This concrete reference demonstrates the full method-to-result workflow out of the box; swap the analyte, column, mobile phase, or detection to match what your lab runs.

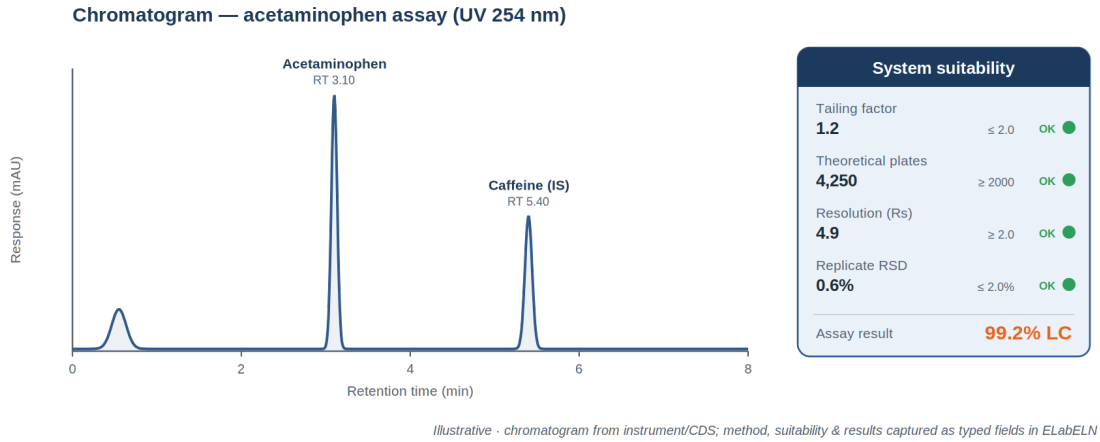

Figure 4. A reverse-phase chromatogram with analyte and internal-standard peaks alongside a system-suitability panel checked against acceptance criteria. Illustrative; the chromatogram is produced by the instrument/CDS, and the method, suitability metrics, and assay result are captured as typed fields in ELabELN.

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7.2 How the Template Handles the Method, Suitability, and Results

The method parameters (column, mobile phase, flow, wavelength, injection volume), the system-suitability metrics (tailing factor, theoretical plates, resolution, replicate RSD, and signal-to-noise for limit standards), and the assay result are all captured as typed fields, and the full sample run — retention times, peak areas, and calculated results — lives in the spreadsheet editor. The raw chromatogram export and integrated peak table attach to the same record. Because the method and suitability data are structured and queryable, trend analysis across batches is straightforward: query every run under a method version and review system suitability and results side by side, rather than treating each batch as an isolated printout.

Element	Default configuration	Editable to
Column	C18, 4.6 × 150 mm, 5 µm	C8, HILIC, phenyl-hexyl
Mobile phase / elution	Phosphate buffer + methanol, isocratic	Gradient elution; other buffers
Detection	UV 254 nm	DAD, fluorescence
Analyte / standard	Acetaminophen; caffeine IS	Any analyte and reference standard
Mode	Routine assay vs. validation (ICH Q2)	Both supported by the same template

Figure 5. The template's default configuration — fully editable for any column, mobile phase, detection mode, or analyte.

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8. Configuring the Template for Your Method

Adapting the template to a different analyte or method is a matter of editing the relevant sections — not rebuilding the structure.

8.1 Swap the Column and Analyte

Change the column chemistry (C18, C8, HILIC, phenyl-hexyl) and dimensions, and set the analyte and reference standard. If the column and standard already exist in the ELabELN compound database, simply re-link them; their lots, certificate, and column-life flow in automatically.

8.2 Change the Mobile Phase and Elution Mode

Edit the mobile-phase composition and move from isocratic to gradient elution by editing the method section. The system-suitability fields apply to either mode.

8.3 Change the Detection

Adjust the detection wavelength, or move from single-wavelength UV to diode-array (DAD) or fluorescence detection, to match your analyte and method.

8.4 Save a Custom Version

Once configured, save your edits as a private template scoped to your lab, or publish back to the ELabELN template library. Every subsequent batch of that assay opens from your configured, version-controlled method, and separate versions can be maintained for different analytes, methods, or regulatory contexts.

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9. Getting Started

ELabELN Standard is a cloud-hosted SaaS deployment typically live within one to two business days of account creation. There is no hardware to buy, no IT project, and no per-seat licensing.

1. **Start an ELabELN account.** Visit elabeln.com/get-started. ELabELN Standard runs on LabLynx's managed cloud infrastructure.
2. **Provision your instance.** LabLynx provisions the instance within one to two business days; you receive a URL, admin credentials, and onboarding documentation.
3. **Load the HPLC template.** From the template library, select the HPLC template and click “Use This Template.” An editable instance opens immediately.
4. **Add your columns, standards, and reagents to the inventory.** Enter your columns, reference and internal standards, and mobile-phase components with lot numbers, certificates, column-life, and 4 °C standard storage locations. This is a one-time setup step.
5. **Link your validated method, IQ/OQ, and SOP.** Upload your validated method, instrument IQ/OQ reference, and system-suitability SOP, and connect them to the template's Links section.
6. **Customize the template for your assay.** Edit the column, mobile phase, wavelength, analyte, and standard, then save as a private team version.
7. **Run your first assay.** Open your saved template, complete the 10-step checklist, record system suitability and the assay result, attach the chromatogram, and have the reviewing manager sign off electronically.

TYPICAL TIMELINE

Day 1: Account requested at elabeln.com/get-started. Day 2–3: Instance provisioned; column/standard/reagent inventory populated; validated method, IQ/OQ, and SOP linked. Day 3–4: Template configured and saved as a private version for your method. Day 4–5: First assay documented in ELabELN with system suitability and result captured and an authorized e-signature.

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9.1 ELabELN Standard vs. ELabELN Suite

Capability	Standard	Suite
HPLC template access	Included	Included
Unlimited users	Included	Included
Audit trail and e-signatures	Included	Included
Column / standard / reagent inventory with lot & column-life	Included	Included
Validated-method, IQ/OQ & SOP linking with version control	Included	Included
Chromatogram + peak-table attachments	Included	Included
LabVia direct HPLC / CDS capture	—	Suite layer
LabDrive chromatogram archive search & versioning	—	Suite layer
LabVista system-suitability trend dashboards	—	Suite layer

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10. Frequently Asked Questions

Can I configure the template for my analyte and column?

Yes. Every section is editable. Swap in a different column chemistry (C18, C8, HILIC, phenyl-hexyl), change the mobile-phase composition or move from isocratic to gradient elution, adjust the detection wavelength or move from UV to DAD or fluorescence, and change the analyte and reference standard. Save your edits as a private template scoped to your lab, or publish back to the ELabELN template library.

Does the template support GMP and ISO 17025 documentation?

The template is designed to support both. System-suitability fields capture the metrics required for compendial methods (tailing factor, theoretical plates, resolution, RSD of replicate injections, signal-to-noise for limit standards). The tamper-evident audit trail captures every method change, every standard prep, and every assay result, supporting the documentation requirements for both ISO 17025 method validation and 21 CFR Part 11 electronic-record retention. Compliance ownership remains with the lab's quality program; the ELN supports it.

How does the template handle method validation versus routine assays?

The template supports both. For validation runs, the structured fields capture the precision, accuracy, linearity, range, LOD, and LOQ measurements per ICH Q2(R1). For routine assays, the same template tracks per-batch system suitability against the validated criteria, with the audit trail showing every assay run that referenced a given method version.

Is it included in every ELabELN plan?

Yes. Every published template in the ELabELN library is available to all subscribers in both the Standard and Suite editions, with unlimited users in either edition and no per-template fee.

Can my whole lab use this template?

Yes. Every ELabELN edition includes unlimited users, so the QC analyst, lab manager, method developer, and reviewing manager can all use the template without per-seat charges. Granular permissions let the lab manager control who can edit method records versus only review them.

How quickly can my lab start running HPLC in ELabELN?

ELabELN Standard cloud deployment is typically live in one to two business days. Once the instance is provisioned, the template loads from the library in a single click, with the method parameters, column, and standard references editable to match the assays your lab actually runs.

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11. Conclusion

The ELabELN HPLC Experiment Template is not simply a digital version of an instrument printout. It is a structured, audit-ready, searchable record that connects to your column and standard inventory, your validated method and SOPs, the sample the assay measured, your instrument and chromatography data system, and the release, method-transfer, and trend workflows the result feeds — and, in the Suite edition, system-suitability trend dashboards. It turns a regulated analytical assay into a record whose method, suitability, and result are captured, comparable, and defensible.

For a laboratory that runs HPLC regularly, the benefit compounds with every batch. Method versions, system-suitability metrics, and assay results accumulate into one queryable history. Every column lot and standard is traceable. Every method version is documented. Every run is timestamped, and every result is authorized — so an aging column or an unrecorded method change can no longer quietly undermine a release decision, and system drift is caught before it costs a batch.

The template is available to all ELabELN subscribers today. A new instance is live in one to two business days, and the first structured assay is typically complete within a week of account creation.

GET STARTED

Visit elabeln.com/get-started to request your ELabELN instance, or contact LabLynx at 866.522.5969 or info@lablynx.com. Load the HPLC template, configure it for your method and analyte, and run your next assay from a tested, audit-ready baseline.

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